

indicating high levels of random measurement error. Three of the SF-36 domains did not distinguish between WHO functional classes. Only two of the SF-36 domains (role physical and general health perceptions) met the full psychometric criteria of the study. In contrast, all CAMPHOR scales exhibited good test retest reliability and distinguished significantly between WHO functional classes. **CONCLUSIONS:** The CAMPHOR has superior psychometric properties, compared to the SF-36, in the assessment of QoL in individuals with PH.

#### PCV93

##### STUDY OF THE USE OF QUALITY OF LIFE QUESTIONNAIRES IN CARDIAC DISEASES IN POLAND

Sieluk J<sup>1</sup>, Zawodnik S<sup>2</sup>, Hermanowski T<sup>3</sup>

<sup>1</sup>Medical University of Warsaw, Warsaw, Masovian, Poland, <sup>2</sup>Medical University of Warsaw, Warsaw, Poland, <sup>3</sup>Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

**OBJECTIVES:** To assess the use of quality of life questionnaires in polish cardiac patients, as well as research methods used by polish authors in terms of international quality of life research guidelines. **METHODS:** Systematic literature review was performed in order to collect publications assessing quality of life in cardiac patients in Poland. Medical databases and the most important health agencies websites were searched for HRQoL assessment guidelines. Inclusion criteria: studies carried in the Republic of Poland; studies in which authors were using HRQoL questionnaires in cardiac patients. Exclusion criteria: Studies carried outside of Poland; studies estimating HRQoL among patients with vascular diseases; case reports; researches and review papers without HRQoL assessment. Based on the international guidelines, "checklist" consisting of 19 statements and questions was created as a basis for data extraction from accessed publications. **RESULTS:** As a result of systematic literature review and inclusion criteria application, 131 polish publications were included in this analysis. 26% of all researches were based on questionnaires designed by the authors for their own needs, of which 71% have never been validated. Results of questionnaires were calculated using official key only in 43% of publications. Among the included studies, 63% assessed HRQoL as a primary endpoint. Observational studies assessing HRQoL in polish cardiac patients without any interventions were the most common (41%). At the same time, 36% of studies were related to surgical intervention. **CONCLUSIONS:** Polish studies assessing HRQoL in cardiac patients often do not meet all the requirements stated in international guidelines. Promoting of the results of this work can increase the awareness of polish authors in terms of proper HRQoL measures.

#### PCV94

##### THE INFLUENCE OF DISEASE-SPECIFIC SYMPTOMS ON THE HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ATRIAL FIBRILLATION

Wilke T<sup>1</sup>, Müller S<sup>2</sup>, Bauersachs R<sup>3</sup>, Breithardt G<sup>4</sup>

<sup>1</sup>Hochschule Wismar, Wismar, Germany, <sup>2</sup>IPAM, Wismar, Germany, <sup>3</sup>Klinikum Darmstadt GmbH, Darmstadt, Germany, <sup>4</sup>University Clinic Muenster, Muenster, Germany

**OBJECTIVES:** To assess the health-related quality of life (HrQoL) in patients with atrial fibrillation (AF) in Germany and to identify the influence of the associated AF-specific symptoms on HrQoL. **METHODS:** HrQoL of AF patients recruited into a prospective cohort study was assessed by using the written version of the SF 36. General HrQoL as well as physical and mental component summary scores were calculated for each patient. Secondly, AF-related symptoms based on the EHRA AF symptoms classification (palpitations, fatigue, dizziness, dyspnea, chest pain, anxiety) were collected by asking each patient to fill out written questionnaires during visiting a GP. To identify the influence of these symptoms on HrQoL, a linear regression was conducted for each component summary score, while controlling for additional socio-demographic/AF-related clinical parameters. **RESULTS:** A total of 526 AF-patients were recruited in 71 study centers (female patients: 45.1%, average age: 73.2 years, average CHA<sub>2</sub>DS<sub>2</sub>-VASc score: 3.8). The average SF-36-physical summary score was 38.6 (SD: 10.4). The average SF-36 mental component score was 46.5 (SD: 11.8). Only 14.8% of the patients reported none of the EHRA-symptoms. The most frequent symptom was fatigue (72.1% of all patients). The results of the first multivariate regression ( $R^2=0.349$ ) showed that the most important factors explaining the SF-36-physical component score were fatigue, chest pain, dizziness and dyspnea. Only two of the control variables had a significant influence on physical HrQoL (age; number of medications taken). In the second estimate addressing mental HrQoL ( $R^2=0.349$ ), none of these factors was significant. The most important factors explaining mental HrQoL were palpitations, dizziness and anxiety. **CONCLUSIONS:** AF patients in real life care have a limited physical/mental HrQoL. AF-related symptoms significantly explain the level of HrQoL. Consequently, in order to increase/maintain the HrQoL of AF patients, it is important to control/improve scores measured for AF-related symptoms.

#### PCV95

##### THE PATIENT'S EXPERIENCE OF NUISANCE BLEEDING AND BRUISING WHILE ON ANTIPLATELET MEDICATIONS FOR ACS

Gwaltney C<sup>1</sup>, Slagle A<sup>2</sup>, Martin M<sup>3</sup>, Mollon P<sup>4</sup>

<sup>1</sup>Invivodata, Inc., Westerly, RI, USA, <sup>2</sup>FDA/CDER/OND, Silver Spring, MD, USA, <sup>3</sup>Health Research Associates, Inc., Seattle, WA, USA, <sup>4</sup>Novartis Pharma AG, Basel, Switzerland

**OBJECTIVES:** Bleeding is a common experience for acute coronary syndrome (ACS) patients who receive anti-platelet medications. "Nuisance" bleeding and bruising – non-life threatening events that occur in the patients' everyday lives and may impact medication adherence – is not often assessed in clinical trials and existing measures may not capture all relevant aspects. In this study, we used qualitative interviews to better understand how patients experience nuisance bleeding and bruising and its impact. **METHODS:** One-hour interviews were conducted using a semi-structured interview guide with patients who had experienced ACS in the

past year. All participants were taking clopidogrel at the time of enrollment into the study and reported experiencing nuisance bleeding and bruising. Most patients were male (70%) and white (80%) and the average age was 63.5 years old. Interview responses were coded using ATLAS.ti software. Data were analyzed by extracting relevant themes emerging from the interviews and by calculating the percent of patients expressing a specific concept related to nuisance bleeding and bruising. **RESULTS:** Prominent features included the amount of bleeding, difficulty stopping the bleeding, and the size and color of bruises. Frequency was an important issue for patients; approximately one-third of patients reported experiencing nuisance bleeding daily. Patients most often reported that bleeding events lasted only minutes, but that bruises often did not heal for weeks. Nuisance bleeding and bruising appeared to have a significant negative impact on the patients' daily lives, as it resulted in behavior changes to avoid bleeding and bruising events and a variety of negative emotions (e.g., embarrassment, frustration, fear). **CONCLUSIONS:** Nuisance bleeding and bruising can have a significant impact on the lives of ACS patients on anti-platelet medications. The data from this qualitative interview study may allow for improved measures of nuisance bleeding and bruising that can be administered in studies examining antithrombotic therapies.

#### PCV96

##### RELATIONSHIP BETWEEN INFLAMMATION AND PATIENT FUNCTIONING IN CARDIOVASCULAR DISEASE: A REVIEW OF THE LITERATURE

Gwaltney C<sup>1</sup>, St. Charles M<sup>2</sup>, Mollon P<sup>3</sup>, Falvey H<sup>3</sup>

<sup>1</sup>Invivodata, Inc., Westerly, RI, USA, <sup>2</sup>Invivodata, Inc., Pittsburgh, PA, USA, <sup>3</sup>Novartis Pharma AG, Basel, Switzerland

**OBJECTIVES:** Patients with cardiovascular disease (CVD) experience a number of symptoms, such as tiredness, that can limit their physical activities and disrupt daily life. Increased inflammation may independently contribute to the experience of these symptoms and functional limitations, in addition to increasing the risk of CVD and acute events. The goal of this study was to perform a qualitative review of published studies that address the link between inflammation and patient functioning among patients with cardiovascular disease. **METHODS:** Articles were identified through MEDLINE and PubMed. Search terms included "inflammation, inflammatory markers, CRP, TNF- $\alpha$ , and interleukins" crossed with "fatigue, depression, physical activity, sleep, function, and cardiovascular." The search returned 938 articles, a total of 112 abstracts were reviewed, and 46 full articles were examined. Of these, 8 addressed patients with chronic or acute cardiovascular disease and were included in the review. **RESULTS:** The articles examined multiple inflammatory markers, including IL-1 $\beta$ , IL-6, TNF- $\alpha$ , CRP, IL-10, IL-8, neopterin, sICAM-1, and IL-1ra. Symptoms and functional limitations measured included fatigue/tiredness, irritability, depression, demoralization, and physical activity/exercise. Significant associations were observed in all 8 studies. The relationship between inflammation, IL-6 in particular, and tiredness was consistently seen. Evidence also supported a relationship with depressed mood, but the association was not uniform across inflammatory markers. Inflammation was also associated with physical activity, with one study showing that exercise reduced hsCRP and inflammatory cytokines. **CONCLUSIONS:** Symptoms and limitations on physical functioning can substantially burden patients with CVD. Although additional research is needed, this review suggests that inflammatory processes may independently contribute to this patient burden. Reducing inflammation may not only reduce the risk of CVD and associated events, but also directly improve symptoms and improve functioning. It will be useful to include outcomes assessing these concepts in trials examining anti-inflammatory treatments in CVD patients.

#### PCV97

##### BURDEN OF DYSPEPSIA AMONG PATIENTS WITH ATRIAL FIBRILLATION IN JAPAN

Kinoshita Y<sup>1</sup>, DiBonaventura MD<sup>2</sup>, Wang ECY<sup>3</sup>, Rossi B<sup>4</sup>, Iwamoto K<sup>4</sup>, Stankus A<sup>5</sup>, Briere JB<sup>6</sup>

<sup>1</sup>Shimane University School of Medicine, Izumo, Shimane, Japan, <sup>2</sup>Kantar Health, New York, NY, USA, <sup>3</sup>Bayer Yakuhin, Ltd., Tokyo, Japan, <sup>4</sup>Bayer Yakuhin, Ltd., Kita-ku, Osaka, Japan, <sup>5</sup>Kantar Health, Princeton, NJ, USA, <sup>6</sup>Bayer Yakuhin, Ltd., Chiyoda-ku, Tokyo, Japan

**OBJECTIVES:** To assess the prevalence and impact of dyspepsia among Japanese Atrial Fibrillation (AF) patients. **METHODS:** The 2008, 2009, and 2010 Japan National Health and Wellness Survey (NHWS) datasets were used in this study. The NHWS is an Internet-based survey administered to the adult population in Japan using a random stratified sampling framework to ensure demographic representativeness. Among patients who reported a diagnosis of AF (N=565), those with comorbid dyspepsia were compared with those without dyspepsia on demographics and health history. These groups were also compared on health status (using the SF-12v2), work productivity (using the WPAI), and health care resource use (physician visits, emergency room [ER] visits, and hospitalizations) in the past six months using multivariate regression modeling and controlling for baseline differences. **RESULTS:** Dyspepsia was the most common non cardiovascular comorbidity, affecting over a third (37.4%) of AF patients. This prevalence was higher than in general population (21.3%). Its presence was not associated with any demographic or general health history variables. However, patients with dyspepsia used more AF medications (2.05 vs. 1.54) and had been diagnosed more recently (9.97 vs. 10.58 years). Adjusting for these differences, patients with dyspepsia reported significantly worse physical health status (PCS scores: 41.32 vs. 45.66) and health utilities (0.70 vs. 0.76) (all  $p<0.05$ ). Those patients also reported significantly more overall work impairment (29.65% vs. 17.02%) and more physician visits (19.35 vs. 12.62), and ER visits (0.40 vs. 0.14) in the past six months (all  $p<0.05$ ). **CONCLUSIONS:** Dyspepsia is common among Japanese AF patients. Even after adjusting for confounding variables, dyspepsia was significantly associated with poorer health sta-